

## **REMARKS**

### **Claim Amendments**

Claims 1 and 31 are currently pending herein. Claims 2, 4, 6-9, 17, 19-30, 33-39, 41, 43-94, 96-98 and 100-146 are canceled herein. Claims 95 and 99 have been amended herein to be dependent from Claim 1. New Claim 147 has been added herein. Support for new Claim 147 can be found throughout the specification and in Claim 42 as originally filed. No new matter has been added.

### **Rejoinder**

It is Applicants belief that Claims 1 and 31 are in condition for allowance and, therefore, respectfully request that withdrawn Claims 3, 5, 10-16, 18, 32, 40, 42, 95, 99 and 147 be rejoined.

### **Rejection For Failure To Comply With 37 C.F.R. §§ 1.821-1.825**

The application has been rejected for failing to comply with the requirements of 37 C.F.R. § 1.821. Specifically, the Office Action states that the application references sequences that lack the proper sequence identifiers.

Applicants respectfully disagree that the specification fails to comply with the requirements of 37 C.F.R. § 1.821. Nucleotide and/or amino acid sequences as used in §§ 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. 37 C.F.R. § 1.821(a)(1) states that nucleotides are intended to embrace only those nucleotides that can be represented using the symbols set forth in WIPO Standard ST.25 (1998), and (a)(2) states that Amino acids are those L-amino acids commonly found in naturally occurring proteins and are listed in WIPO Standard ST.25 (1998). Sequence identifiers are only required where the sequence is disclosed. Since the disclosure for Figures 7-12, 15-17, 19-20 and 25-30 do not meet these definitions the application complies with the Sequence Listing requirements.

Furthermore, Figures 2 and 23 were amended in a Preliminary Amendment mailed to the USPTO on May 13, 2004, and Figures 15-17 and 19-20 were amended herein in a Preliminary Amendment mailed to the USPTO on to match the oligonucleotide number shown in the figure with the oligonucleotide number as shown in the Specification.

One skilled in the art can match the number in the Figures and Tables with the sequence identifier properly attached to the disclosed sequence within the application. Reconsideration and withdrawal of the rejection are respectfully requested.

**Rejection of Claims 1 and 31 Under requirements of 35 U.S.C. §103(a)**

Claims 1 and 31 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kandimalla, Cook, Rappaport, Simmonds, Yu, Teng and Cook. Specifically, the Office Action states that all the claimed elements were known in the prior art and that it would have been obvious, in view of Cook, Rappaport, Simmonds, Yu, Teng and Cook, to replace a guanosine or cytosine base with the simple substitution of an analog with no change in their respective functions, and which would have yielded predictable results.

Applicants respectfully disagree. The burden for establishing patentability over the described genera shifts to the Applicant only after the PTO has established a *prima facie* case of obviousness over the disclosed genera. For the following reasons, no *prima facie* case of obviousness has been established by the instant Office Action.

As a starting point, this currently maintained rejection is far afield from the standards for analysis required by 35 U.S.C. §103, and as interpreted by the Supreme Court in *Graham v. John Deere of Kansas City*, 148 U.S.P.Q. 459 (1996). In particular, the presently maintained rejection ignores the admonition that an obviousness determination must consider “the claimed invention as a whole”. *Application of Aufhauser*, 158 U.S.P.Q. 351, 352 (C.C.P.A. 1968). Thus, mere identification of limitations of the claimed invention from many disparate references to declare the combination to be obvious is insufficient. Rather, one of ordinary skill in the art must have been motivated to select the references and to combine them. (See *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1336 (Fed.Cir.2006)). The cited references fail to provide this motivation.

Applicants would like to point out that although Cook, Rappaport, Simmonds, Yu, Teng and Cook generally describe various nucleoside analogs, these references fail to teach or suggest modification of a CpG dinucleotide with these analogs. This is not a trivial omission by the cited references, especially considering that it is the CpG dinucleotide that confers immunostimulatory properties to the oligonucleotide. In fact, by teaching that the analogs do not affect the functioning of the nucleotide in any substantial manner, Cook, Rappaport, Simmonds, Yu, Teng

and Cook clearly teach away from this substitution. Therefore, the cited references fail to provide one skill in the art the motivation to modify the CpG dinucleotide with the described nucleoside analogs to obtain the claimed invention.

Furthermore, the Office Action bases its rejection on the mere fact that "all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in the respective functions, and the combination(s) would have yielded predictable results to one of ordinary skill in the art at the time of the invention". However, this is an insufficient basis for the rejection as it looks at the claims, not at the time the application was filed, but through the improper use of hindsight to identify claimed elements within the prior art without providing the requisite motivation to combine them. That which is within the capabilities of one skilled in the art is not synonymous with obviousness.

The Office Action fails to consider the teachings of the specification, as supported by the examples and data therein, that modifications to a CpG dinucleotide can alter the immune response profile of the CpG-containing oligonucleotide in a non-predictable fashion. It also ignores the fact that the cited references merely describe nucleoside analogs and fails to teach or suggest CpG-containing oligonucleotides or modifications of the CpG dinucleotide. It also ignores the fact that the instantly claimed invention is directed towards an immunomer comprising an "RpG" motif, wherein R is synthetic **purine** motif. Such a modification to the CpG dinucleotide was neither taught nor suggested by the prior art.

As such, Claims 1 and 31 are patentable over the cited references. Reconsideration and withdrawal of the rejection are respectfully requested.

**Provisional obviousness-type double patenting**

Claims 1 and 31 are provisionally rejected over various claims of copending Application Nos. 10/361,111; 10/865,245; 10/925,873; 11/153,054; and 11/174,002.

As stated by the Examiner, this is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Please note that, with regards to patent term, U.S. Application Nos. 10/361,111; 10/865,245; 10/925,873; 11/153,054; and 11/174,002 are the later filed applications.

Therefore, if this provisional double patenting rejection is the only remaining rejection in the application, Applicants request that the Examiner withdraw the rejection in the instant

[earlier filed] application thereby permitting this application to issue without need of a terminal disclaimer. (See MPEP §804(I)(B)). Applicants will then consider filing a Terminal Disclaimer or take any other action deemed necessary in the later filed, copending applications.

Claims 1 and 31 are provisionally rejected over various claims of copending Application Nos. 10/279,684 (now 7,276,489), 10/694,383 and 10/694,586.

Applicants respectfully disagree. The claims in the '489 patent, the '383 application and the '586 application relied upon by the Office Action recite an immunostimulatory oligonucleotide comprising a "YpZ" motif, wherein the Y moiety is a non-natural pyrimidine. Claim 1 of the instant application is directed towards an immunomer comprising an "RpG" motif, wherein R is synthetic purine motif. Such a modification was neither taught nor suggested by the references cited in the Office Action. Reconsideration and withdrawal of the rejection is respectfully requested.

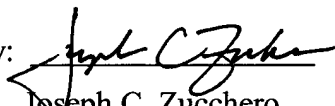
### CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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